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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,347	10/12/2001	Anabella Villalobos	PC10803A	1717

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/976,347	VILLALOBOS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 01 April 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) 12-22 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-11 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 21 October 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

Applicant's election without traverse of Group I, claims 1-11, drawn to a pharmaceutical composition comprising an acetylcholinesterase inhibitor and an inverse agonist of GABA<sub>A</sub> α1 and/or α5 receptor subtype in Paper No. 6 is acknowledged.

Accordingly, claims 12-22 are withdrawn from consideration since they are non-elected invention.

### ***Specification***

The use of the trademark ARICEPT, EXELON, SYNAPTON, REMINYL and PROMEM has been noted in this application. (see specification pages 7, 13, 14 and 22). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11 contains the trademark/trade name AERICEPT and EXELON. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular

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material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the Acetylcholinesterase inhibitors and, accordingly, the identification/description is indefinite. It is suggested to delete the trade name.

Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The parenthetical terms renders the claims indefinite since it renders redundancy. It is also redundant to use two different names for the same compound (i.e. donepezil and E2020). It is suggested to use only one appropriate chemical name.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicants' admission.

Applicants admit on "Background of the Invention" on page 2, lines 15-20, that the combinations of a GABA<sub>A</sub> cognitive enhancer and an AchE inhibitor results in greater (additive/synergistic) efficacy or cognitive/behavioral improvement in the treatment of the disorders associated with cognitive impairment in comparison to the efficacy displayed by either agent alone.

The difference between Applicants admission and the claimed invention is the specified active GABA<sub>A</sub> cognitive enhancer set forth in the claims:

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It would have been obvious to one of ordinary skill in the art to combine GABA<sub>A</sub> cognitive enhancer and an AchE inhibitor in a pharmaceutical formulation because the combination of GABA<sub>A</sub> cognitive enhancer and an AchE inhibitor are well known to have greater (additive/synergistic) efficacy or cognitive/behavioral improvement. One of ordinary skill in the art would have been motivated to formulate GABA<sub>A</sub> cognitive enhancer and an AchE inhibitor to achieve additive/synergistic effect in treatment of a patient suffering from cognitive disorders.

Absent any evidence to contrary, there would have been reasonable expectation of success in formulating GABA<sub>A</sub> cognitive enhancer and an AchE inhibitor in a pharmaceutical composition to achieve convenient mono-drug regimen with greater effect of each agents given alone in treatment of cognitive disorder patients.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albaugh et al. (U.S. Patent No. 6,143,760) in view of Bruns et al. (1999).

Albaugh et al. teach Applicants' GABA<sub>A</sub> inverse agonists set forth in claims 1-11 useful for treating cognitive disorders. (abstract, columns 2-3, column 48, claim 38).

Albaugh et al. do not teach the combination of the GABA<sub>A</sub> inverse agonists and acetylcholinesterase inhibitors in a pharmaceutical composition and the functional efficacy set forth in claims 1-5.

Burns et al. teach acetylcholinesterase inhibitor, donepezil useful for treating cognitive disorder.

It would have been obvious to one of ordinary skill in the art to employ combinations of the GABA<sub>A</sub> inverse agonists and acetylcholinesterase inhibitors in a pharmaceutical composition to treat cognitive disorders because all the components are well known individually for treating cognitive disorders. It would be expected that the combination of components would treat cognitive disorders as well. The motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPA 1980)). It would have been *prima facie* obvious to combine the GABA<sub>A</sub> inverse agonists and acetylcholinesterase inhibitors cojointly in a formulation to treat cognitive disorders. The functional efficacy set forth in claims 1-5 is obvious property of the same GABA<sub>A</sub> inverse agonists to be utilized in above modified pharmaceutical composition.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

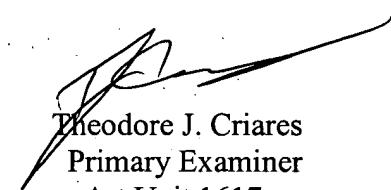
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Theodore J. Criares  
Primary Examiner  
Art Unit 1617

jm  
June 11, 2003